

AD_____

Award Number: W81XWH-08-2-0047

$$\begin{array}{c} \dot{A} \\ \dot{A} \end{array}$$

TITLE: Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women

$$\begin{array}{c} \acute{A} \\ \acute{A} \end{array}$$

PRINCIPAL INVESTIGATOR: Ronald Acierno, PhÈDÈ

CONTRACTING ORGANIZATION: Oãää→æb\~^ĀĤæbæää´āÄØ`b\↔\|\æÃ
 ÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄOöää→æb\~^ÊÄUÖÄGİH€Ğ

REPORT DATE: April 2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;

[illegible] \acute{A} \acute{A}

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) Cr tkl4234		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 1 April 2011-31 March 2012	
4. TITLE AND SUBTITLE Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-08-2-0047	
				5c. PROGRAM ELEMENT NUMBER	
				5d. PROJECT NUMBER	
6. AUTHOR(S) Tqpcrf 'Cekgtpq.'Rj (F 0 Gtlec' l wgp.'Rj (F 0 Wendy Muzzy, B080				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Charleston Research Institute Charleston, SC 29403				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) US Army Medical Research Fort Detrick, Maryland 1702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This report describes key research accomplishments for Innovative Service Delivery for Secondary Prevention of PTSD between 4/1/11 and 3/31/12. This report focuses on the primary objectives for our fourth year including: a) recruitment and enrollment, b) the development and implementation of an efficient, sustainable, study-referral infrastructure, and c) presentation of the project at national conferences and submission and preparation of initial manuscripts. Additionally, we provide a detailed description of the study-related activities that occurred between 01/01/12 and 3/31/12.					
15. SUBJECT TERMS PTSD, OIF/OEF, Telemedicine, Behavioral Activation, Therapeutic Exposure, DOD/VHA research collaborations					
16. SECURITY CLASSIFICATION OF: U			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES ***** 34	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction	2
Body	2
Key Research Accomplishments	5
Reportable Outcomes	6
Conclusion	9
References	10
Appendices.....	10

INTRODUCTION:

The current project has two primary objectives: 1) evaluate the effectiveness of an intervention to prevent the functional impairment associated with PTSD symptoms in post-deployed OIF/OEF service men and women, and 2) determine whether or not this program delivered via telepsychology will be as effective as in-person treatment. Behavioral Activation and Therapeutic Exposure (BA-TE) is an eight-session, manualized treatment program. Using a between-groups, repeated measures design, study participants will be randomized to one of two treatment conditions: BA-TE delivered via telepsychology (BA-TE-T), or BA-TE delivered in-person (BA-TE-IP). Participants will be assessed across primary and secondary outcome variables at five time points (pre-treatment, mid-treatment, post-treatment, and 3- and 12-month follow up).

BODY:

The major tasks of the S.O.W. include (1) **recruit** 200 active duty or veteran participants with PTSD or Sub-Threshold PTSD and randomly **assign** to either in person or televideo based treatment for PTSD; (2) collect measures of PTSD and other psychopathology, attendance, patient satisfaction and cost at pre-treatment, post-treatment, and follow-up. Note that our S.O.W. has been amended and approved to address the more prevalent problem of chronic PTSD by including up to 33% of Vietnam Veterans, in addition to OIE/OEF and Persian Gulf Veterans.

Report: 4 Year Point Data Analysis

Between 04/01/2011 and 03/31/2012, 408 participants were screened and 58 were enrolled, bringing our total enrollment to date since the initiation of study procedures on 10/08/2008 to 167. Additionally, 36 participants completed post-test assessment (85 total), 33 completed three-month follow-up (69 total), and 20 completed 12-month follow-up (42 total).

Participants were predominantly male (91%), White (50.7%) followed by Black (44%) and then Hispanic/Other (5.2%), and had a mean age of 41.0 years ($SD = 14.4$). Theatre was predominantly OIF/OEF (60.4%), followed by Vietnam (20.1%) and then Persian Gulf (19.5%). All participants endorsed symptoms consistent with either PTSD or subthreshold PTSD on the CAPs.

Clinical outcomes: Baseline to one-week post treatment

To evaluate the overall efficacy of BA-TE, we ran analyses on the PTSD Checklist-Military Version (PCL-M) and Beck Depression Inventory, Second Edition (BDI-II) for the entire sample. These analyses revealed significant within subject pre- to post-treatment reductions on the primary symptom measures. Consistent with

hypotheses, analyses revealed significant reductions in PTSD and Major Depressive Disorder (MDD) symptoms over time, but no significant time by condition interactions.

Figure 1: PCL-M Score Pre-Post (N = 75)

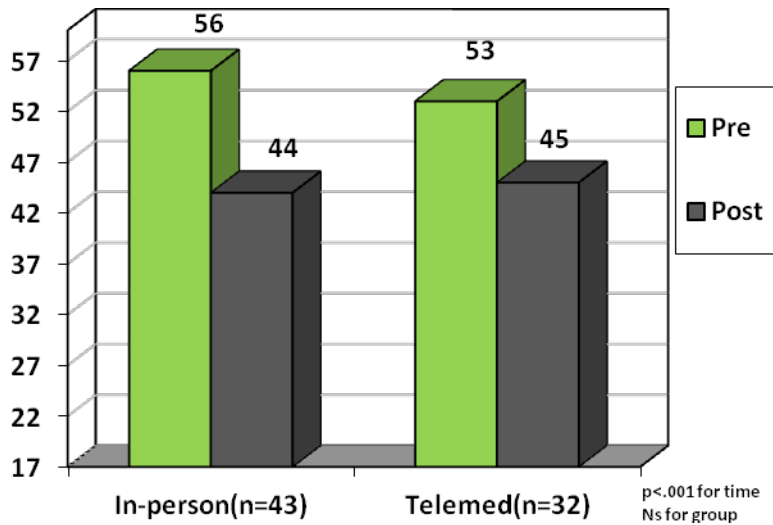
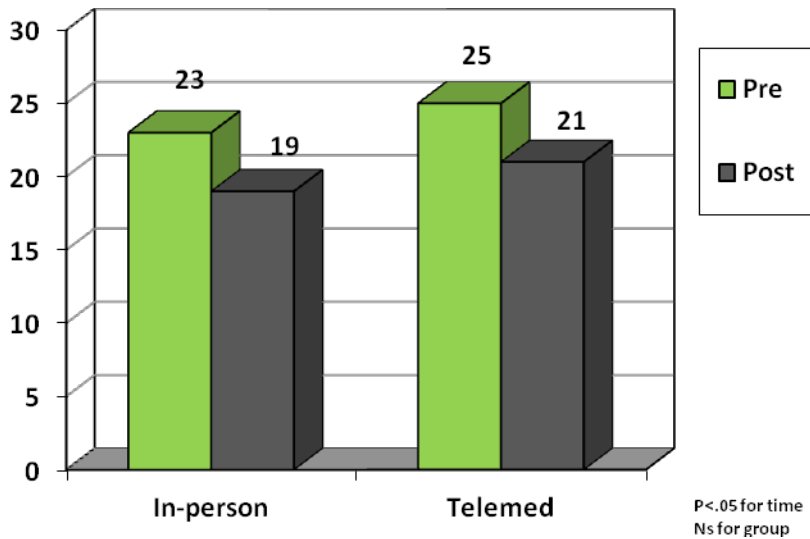


Figure 2: BDI Score Pre-Post (N = 75)



Trends at three-month follow-up

To date, 69 participants have completed the three-month follow-up assessment. Although tests of significance across condition are premature at this stage of the study, initial data suggest that participants maintain therapeutic gains three months post-treatment completion.

Trends at twelve-month follow-up

To date, 42 participants have completed the twelve-month follow-up assessment. Although tests of significance across condition are premature at this stage of the study, initial data suggest that participants maintain therapeutic gains twelve months post-treatment completion.

Figure 3: PCL Scores across Time (N=33)

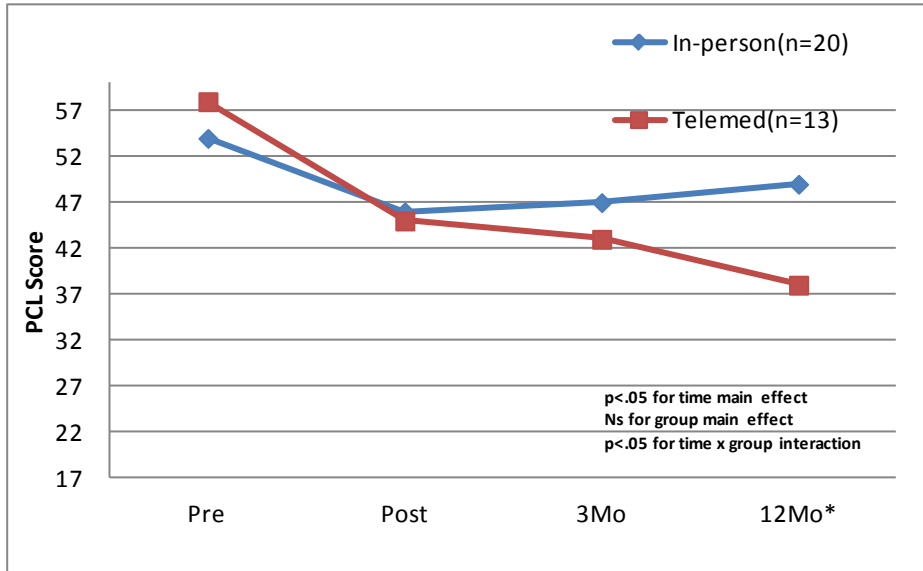
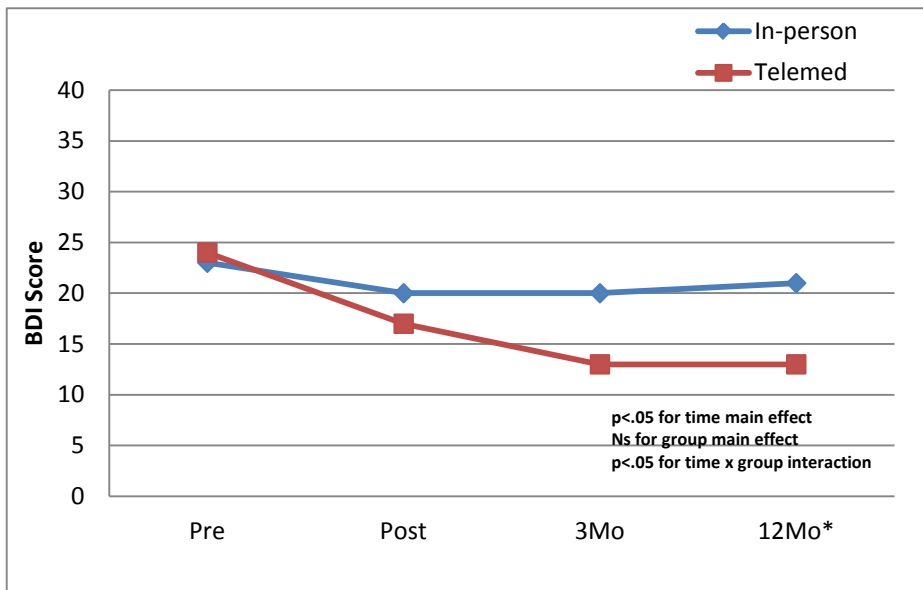


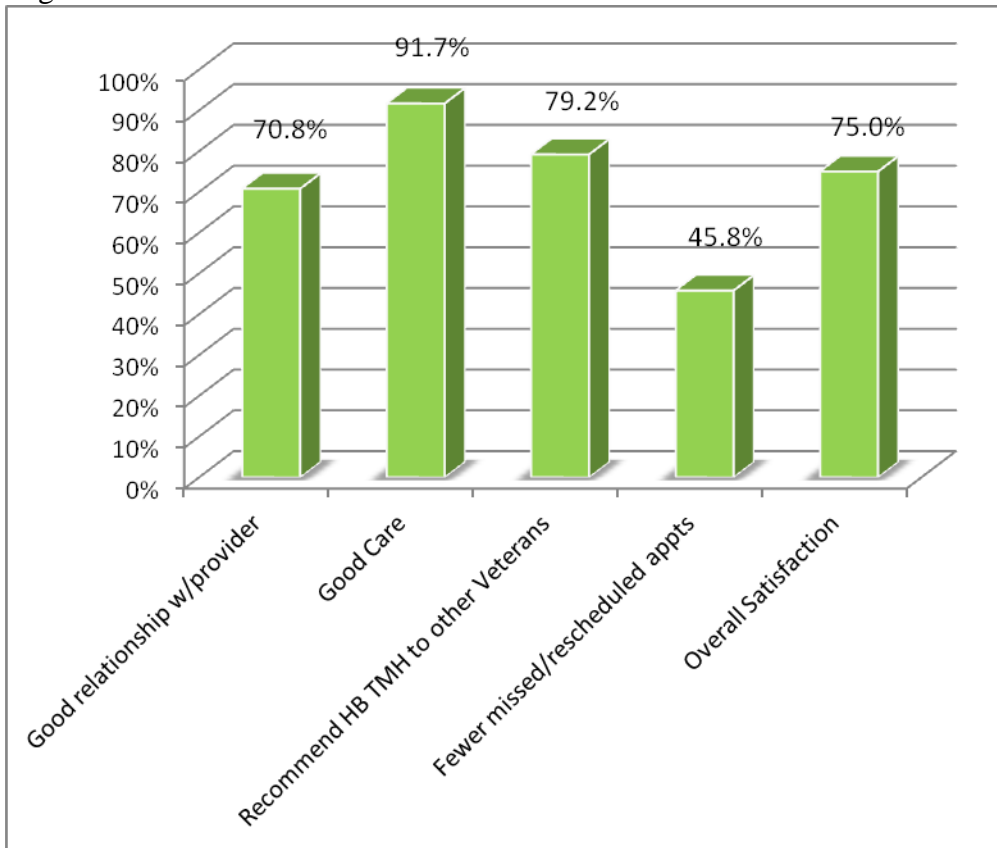
Figure 4: BDI Scores across Time (N=33)



Patient Satisfaction

Of the 24 patients who completed the patient satisfaction survey, 70.8% agreed that their relationship with the clinician was the same using telehealth as it was in person. 91.7% agreed that they received good care via telehealth . 79.2% were satisfied and would recommend home-based telehealth to other Veterans. 44.4% said that access to HB TMH led to fewer/missed rescheduled appointments.

Figure 5: Patient Satisfaction



KEY RESEARCH ACCOMPLISHMENTS:

- 167 participants have been enrolled to date; 85 participants have completed post-treatment assessment; 69 participants have completed 3-month follow-up; and 42 participants have completed 12-month follow-up
- An amendment to the statement of work to allow the enrollment of Vietnam and Persian Gulf veterans into the study was approved. The recent inclusion of Vietnam Veterans has enhanced recruitment success.

- Team representatives established relationships with clinicians at our primary care clinic annexes located in the Trident Hospital and the Charleston Naval Weapons Station.
- Team representatives established relationships with providers at the Goose Creek satellite clinic to establish a new recruitment path and increase enrollment.
- Research staff implemented a postcard and phone call recruitment initiative; Veterans diagnosed with PTSD and receiving services at community-based outpatient clinics (e.g., Savannah, Myrtle Beach, Beaufort) are contacted via postcards/telephone to inform them of treatment opportunities through this study.
- Research staff has utilized print and radio advertisements to recruit additional participants.
- Staff continues to meet weekly with Dr. Acierno (Principal Investigator) for clinical supervision. Other clinical training/supervisory experiences included attending weekly Grand Rounds seminars, assessment training seminars, and providing ongoing opportunities for clinical staff to shadow senior-level clinicians during therapy.
- Eight manuscripts were accepted for publication (see next section).
- We presented preliminary findings at several national and regional conferences (see next section).

REPORTABLE OUTCOMES:

- 3 manuscripts have been published, and an additional 5 manuscripts are currently in press:

Acierno, R., Gros, D.F, Strachan, M., Frueh, BF (in press). The Next Step: Moving Combat-Related PTSD Care out of the Clinic and into the Home (or Boat, or Hotel, or Car [Parked]). *Clinicians Research Digest*.

Gros, D.F., Price, M., Strachan, M., Yuen, E.K., Milanak, M.E., & Acierno, R. (In Press). Behavioral Activation and Therapeutic Exposure (BA-TE): An Investigation of relative symptom changes in PTSD and depression during the course of integrated behavioral activation, situational exposure, and imaginal exposure techniques. *Behavior Modification*.

Gros, D.F., Strachan, M., Ruggiero, K.J., Knapp, R.G., Frueh, B.C., Egede, L.E., Lejuez, C. W., Tuerk, P. W., & Acierno, R. (2011). Innovative service delivery for secondary prevention of PTSD in at-risk OIF-OEF service men and women. *Contemporary Clinical Trials*, 32, 122-128.

- Gros, D.F., Veronee, K., Strachan, M., Ruggiero, K.J., & Acierno, R. (2011). Managing suicidality in home-based telehealth. *Journal of Telemedicine and Telecare*, 17, 332-335.
- Price, M., Gros, D. F., Strachan, M., Ruggiero, K. J., Acierno, R. (in press). Combat experiences, pre-deployment training, and outcome of exposure therapy for PTSD in operation enduring freedom/operation Iraqi freedom veterans. *Clinical Psychology & Psychotherapy*.
- Price, M., Gros, D. F., Strachan, M., Ruggiero, K. J., Acierno, R. (in press). Social support in exposure therapy for OEF/OIF veterans: A preliminary investigation. *Psychological Trauma: Theory, Research, Practice, and Policy*. doi: 10.1037/a0026244
- Strachan, M., Gros, D., Ruggiero, K., Lejuez, C. & Acierno, R. (in press). An integrated approach to delivering exposure-based treatment for symptoms of PTSD and depression in OIF/OEF Veterans: Preliminary findings. *Behavior Therapy*.
- Strachan, M., Gros, D.F., Yuen, E., Ruggiero, K.J., Foa, E.B., & Acierno, R. (2012). Home-based telehealth to deliver evidence-based psychotherapy in veterans with PTSD. *Contemporary Clinical Trials*, 33, 402-409.
- The research team presented at many national/regional conferences:
- Price, M., Gros, D. F., Strachan, M., Ruggiero, K. J., Acierno, R. (2011, November). *The role of social support in the treatment of PTSD in OEF/OIF veterans*. Poster presented for the Disaster & Trauma Special Interest Group at the 45th annual meeting of for the Association for Behavior and Cognitive Therapy, Toronto, Canada.
- Price, M., Strachan, M., Gros, D., Ruggiero, K., Acierno, R. *Combat Experiences, Pre-deployment Training, and Outcome of Exposure Therapy for PTSD in Operation Enduring Freedom/Operation Iraqi Freedom Veterans*. (2011, November). Poster presented for the Disaster & Trauma Special Interest Group at the 45th annual meeting of for the Association for Behavior and Cognitive Therapy, Toronto, Canada.
- Strachan, M., Price, M., Gros, D.F., Ruggiero, K.J., Acierno, R. (November, 2011). *Combat experiences, pre-deployment training, and outcome of exposure therapy for PTSD in OIF/OEF veterans*. Poster presentation at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, Toronto, ON.

- Zeigler, S., Welsh, K., Yuen, E., Strachan, M., Gros, D.F., M., Price, M., Acierno, R. (November, 2011). *Home-based telehealth delivery of exposure therapy to veterans with PTSD living in federally designated rural areas*. Poster presentation at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, Toronto, ON.
- Price, M., Gros, D. F., Strachan, M., West, J. S., Ruggiero, K. J., Acierno, R. (2011, October). *Enhancing behavioral interventions for PTSD in Operation Enduring Freedom/Operation Iraqi Freedom Veterans: Influence of personal and environmental factors*. Poster presented at the Perry V. Halushka Student Research Day, Charleston, SC.
- Acierno, R. (2011, May). *Emerging technologies and new applications for telemental health*. Paper presented at the 2011 American Telemedicine Association in Tampa, FL.
- Strachan, M., Parker, J., Warner, C., Muzzy, W., Welsh, K., Boswell, J., Lejuez, C., & Acierno, R. (March, 2011). *Creating a Collaborative Infrastructure for PTSD Research*; Seminar presented at Armed Forces Health Protections Conference, Hampton Roads, Virginia.
- Strachan, M., Parker, J., Warner, C., Welsh, K., Muzzy, W., Boswell, J., Lejuez, C., & Acierno, R. (March 2011). *Building a Collaborative Infrastructure for Research: Lessons Learned*. Paper presented at the 13th Annual Armed Forces Public Health Conference, Hampton Roads, VA.
- Strachan, M., Brown, C., Veronee, K., Welsh, K., Price, M., Gros, D.F., & Acierno, R. (March 2011). *Legal issues relevant to the diagnosis and treatment of PTSD in OIF/OEF populations*. Poster presented at the International Congress of Psychology and Law, Miami, FL.
- Acierno, R. (November 2010). *Two home based telemedicine treatments of PTSD*. Symposium paper presented at the ABCT 44th Annual Convention in San Francisco, CA.
- Strachan, M., Gros, D.F., Ruggiero, K.J., Lejuez, C.W., Tuerk, P.W., & Acierno, R. (November 2010). *Predictors of patient satisfaction in OEF/OIF Veterans with posttraumatic stress disorder*. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.
- Price, M., Strachan, M., Gros, D.F., Ruggerio, K.J., Acierno, R. (November 2010). *Examination of PTSD and depression treatment response for Behavioral Activation and Therapeutic Exposure*. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.

Veronee, K., Gros, D.F., Strachan, M., Price, M., Ruggiero, K.J., & Acierno, R. (November 2010). *Managing suicidality in home-based telehealth exposure therapy for combat-related PTSD: A case presentation of an OEF Veteran*. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.

Gros, D.F., Strachan, M., Ruggiero, K.J., Tuerk, P.W., Lejuez, C.W., & Acierno, R. (November 2010). *Predictors of treatment completion in OEF/OIF Veterans with posttraumatic stress disorder*. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.

Acierno, R. (February 2010). *Secondary prevention of PTSD in at risk OIF-OEF service men and women: BA-TE via HOME based telemedicine*. Paper presented at the MOMRP/CDMRP PTSD IPR Meeting.

Price, M., Gros, D. F., Strachan, M., Tuerk, P. W., Yoder, M., Ruggerio, K. J., Egede, L. E., Lejuez, C.W., Acierno, R. (February 2011). *Comparison of general health outcomes for African Americans and Caucasians after outpatient treatment for PTSD*. Poster presented at the VA HSR&D 2011 National Meeting, Baltimore, MD.

- Workshops/Training:
 - Dr. Acierno delivered BA-TE training (for use with active duty personnel) to the staff at Joint Base Lewis-McChord in Seattle, Washington (December 2011).
 - Study staff is invited to give a workshop on Behavioral Activation and Therapeutic Exposure for the Armed Forces Public Health Convention (June 2012) .

CONCLUSION:

Recruitment has increased dramatically with the activation of additional recruitment sites and inclusion of Vietnam Veterans.

Preliminary results are consistent with current literature that suggests behavior therapies can be safely and effectively implemented via home-based telehealth technology and that telehealth service delivery yields reductions in symptomatology that are comparable to in-person service delivery. Participants who receive behavior therapy via telehealth report comparable treatment satisfaction, credibility, and service delivery perceptions to patients who receive exposure therapy via conventional in-person service

delivery. Furthermore, preliminary results find that participants in both conditions appear to maintain their treatment gains at 3-month and 12-month follow-up.

Thus far, study findings are encouraging. On measures of both PTSD and MDD, within group improvements are evident, but no differences between telemedicine and in person conditions are evident. The latter findings are tempered, however, because power is still low relative to that suggested as necessary in non-inferiority designs. Nonetheless, lack of significant differences between modalities, with significant improvement within both modalities is worthy of note.

REFERENCES:

None

APPENDICES:

The 8 research articles and 16 research presentations are available upon request.